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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,534	04/15/2004	G. Ian Rowlandson	IT140825 (5024-00118)	8247
26753 7590 04/11/2007 ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 EAST WISCONSIN AVENUE, SUITE 1100 MILWAUKEE, WI 53202			EXAMINER HELLER, TAMMIE K	
			ART UNIT	PAPER NUMBER
			3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/825,534

Applicant(s)

ROWLANDSON, G. IAN

Examiner

Tammie Heller

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7,9,10,12-15,17,18 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7,9,10,12-15,18 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed on March 27, 2007 has been received and considered. By this amendment, claim 17 is amended and claims 1, 3, 5, 7, 9, 10, 12-15, 17, 18, and 20 are now pending in the application.

Response to Arguments

2. Applicant's arguments, see page 6, line 9-page 7 line 21, filed March 27, 2007, with respect to the rejection of claim 17 under 35 USC 102(e) as being anticipated by Lozier have been fully considered and are persuasive. The rejection of claim 17 has been withdrawn.

3. Applicant's further arguments filed March 27, 2007 have been fully considered but they are not persuasive.

4. Regarding the rejection of claims 1, 5, 7, 9, 10, and 12-15 under 35 USC 103(a) as being unpatentable over Mischynski in view of Lozier. Applicant argues that neither Mischynski nor Lozier disclose comparing patient data to stored patterns to determine a measurement with an analysis module or comparing this measurement to a range to determine a correlation. The Examiner respectfully disagrees, as Mischynski discloses integrated circuit 220 including medical information analyzer 230, data store 240, parameter analyzer 250, and abnormality identifier 260 (see Figures 1a-b and 3). Medical information analyzer 230 and parameter analyzer 250 act to compare patient data to stored patterns and determine a measurement (see paragraphs 64-67). Further, the abnormality identifier 260 and the parameter analyzer 250 act in concert to compare the measurement obtained to a range to determine a correlation reflecting the level of

heart disease (see paragraphs 68-69). Therefore, Mischynski compares patient data to stored patterns to determine a measurement with an analysis module and compares this measurement to a range to determine a correlation. Thus the combination of Mischynski and Lozier compares patient data to stored patterns to determine a measurement with an analysis module and compares this measurement to a range to determine a correlation, and therefore this combination discloses each and every aspect of the claimed invention.

5. Regarding the rejection of claims 3 and 18 under 35 USC 103(a) as being unpatentable over Mischynski in view of Lozier, and further in view of Guerrero, Applicant argues that Guerrero fails to disclose a decision support module, a diagnosis module configured to generate a single report based on data acquired from a plurality of medical devices, wherein the single report includes image data, image pattern, image correlation, image measurements, mathematical measurement, parameter value, and a range, or a single report including recommended treatment and a recommended follow-up test. As discussed with regards to independent claims 1 and 12 above, Mischynski discloses a decision support module, therefore the combination of Mischynski, Lozier, and Guerrero discloses a decision support module. Further, as currently written, neither claim 3 nor claim 18 require the generation of a single report based on data acquired from a plurality of medical devices, wherein the single report includes image data, image pattern, image correlation, image measurements, mathematical measurement, parameter value, and a range. Therefore, Applicant's argument that Guerrero fails to disclose this requirement is without basis in the currently filed claims and hence moot.

Finally, as currently written, neither claim 3 nor claim 18 require a single report including recommended treatment and a recommenced follow-up test. Therefore, Applicant's argument that Guerrero fails to disclose this requirement is without basis in the currently filed claims and hence moot.

6. Regarding the rejection of claim 20 under 35 USC 103(a) as being unpatentable over Mischynski in view of Guerrero, Applicant argues that for the same reasons as those for independent claims 1 and 12, claim 20 is allowable. However, as discussed above, independent claims 1 and 12 are not allowable, and therefore the rejection of claim 20 as being unpatentable over Mischynski in view of Guerrero stands.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 5, 7, 9, 10, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mischynski et al. (U.S. 2002/0188214, previously cited), herein Mischynski, in view of Lozier, previously cited. Regarding claims 1 and 12, Mischynski discloses a device and process for analyzing a medical condition of a patient that includes acquiring patient data, comparing the patient data to stored patterns to determine a measurement with an analysis mode, comparing the measurement to a range to determine a correlation with a decision support module, and diagnosing a sudden cardiac risk score (see Figure 1A). Further, Mischynski discloses integrated

circuit 220 including medical information analyzer 230, data store 240, parameter analyzer 250, and abnormality identifier 260 (see Figures 1a-b and 3). Medical information analyzer 230 and parameter analyzer 250 act to compare patient data to stored patterns and determine a measurement (see paragraphs 64-67). Further, the abnormality identifier 260 and the parameter analyzer 250 act in concert to compare the measurement obtained to a range to determine a correlation reflecting the level of heart disease (see paragraphs 68-69). Therefore, Mischynski compares patient data to stored patterns to determine a measurement with an analysis module and compares this measurement to a range to determine a correlation. However, Mischynski discloses that the patient data is acquired in real time from sensor electrodes positioned on the patient's body. Lozier discloses a system that assesses cardiac patients to evaluate their risk for sudden cardiac death. Lozier utilizes a plurality of medical equipment databases to acquire the patient data in order for the patient data to be accessible and able to be analyzed by physicians at different locations at different times (see paragraphs 5 and 11). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to acquire patient data from a plurality of medical equipment databases, as taught by Lozier, to carry out the invention of Mischynski in order to allow the system to be universally used by physicians at different locations at different times, thereby allowing the patient's risk of sudden cardiac death to be assessed by a plurality of physicians.

9. Regarding claim 5, Mischynski discloses that the patient data includes electrocardiogram data (see paragraph 13).

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10. Regarding claim 7, Mischynski discloses that the patient data includes a mathematical measurement based on a parameter value (see paragraph 19).

11. Regarding claim 9, Mischynski discloses that diagnosing the sudden cardiac death risk score is based on an ECG correlation or a mathematical correlation (see paragraph 19 and 20).

12. Regarding claim 10 and 13, Mischynski discloses sending the electrogram data or the sudden cardiac death risk score to a remote storage and processing device (see Figure 1A).

13. Regarding claims 14 and 15, Mischynski discloses integrated circuit 220 and 221 that includes medical information analyzer 230 and abnormality identifier 260 that act as a pattern recognition module and a mathematically relationship module to analyze the ECG data obtained (see Figures 1, 3, and 4 and paragraph 19).

14. Claims 3 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mischynski in view of Lozier as applied to claims 1, 5, 7, 9, 10, and 12-15 above, and further in view of Guerrero, cited in previous Office Action. Mischynski in view of Lozier discloses the invention essentially as claimed, but fails to disclose the use of patient image data to produce the sudden cardiac death score. Guerrero discloses a method of analyzing biological signals via a computerized visual analysis technique, CVAT. Guerrero further discloses that CVAT, in conjunction with Holter monitoring, is an effective method of detecting an increased risk of arrhythmia and sudden cardiac death (see col. 24, ln. 54-56). Therefore, it would have been obvious to one having ordinary

skill in the art at the time of the invention to utilize the CVAT method of Guerrero in conjunction with the invention of Mischynski in view of Lozier in order to provide a method of detecting sudden cardiac death, and thus provide a more accurate sudden cardiac death risk score.

15. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mischynski in view of Guerrero. Mischynski discloses a device and process for analyzing a medical condition of a patient that includes an acquisition module operable to acquire ECG data, an analysis module operable to calculate a plurality of measurements based on the ECG data, a decision support module that analyzes the plurality of measurements and determines a level of heart disease, and a diagnosis module to generate a sudden cardiac death score based on the level of heart disease (see Figure 1A). However, Mischynski fails to disclose acquiring image data that can be utilized by the analysis module. Guerrero discloses a method of analyzing biological signals via a computerized visual analysis technique, CVAT. Guerrero further discloses that CVAT, in conjunction with Holter monitoring, is an effective method of detecting an increased risk of arrhythmia and sudden cardiac death (see col. 24, ln. 54-56). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize the CVAT method of Guerrero in conjunction with the invention of Mischynski in order to provide a method of detecting sudden cardiac death, and thus provide a more accurate sudden cardiac death risk score.

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Conclusion

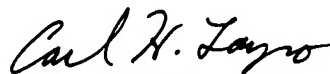
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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